

## URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

**Subject:** ExacTrac Dynamic Radiation Therapy Patient Positioning System:  
 For high dose treatments, potential patient movement might be displayed to the user with a delay

**Product Reference:** ExacTrac Dynamic versions 1.0.0, 1.0.1, 1.0.2

**Date of Notification:** April 29, 2021 (Update to the Notification of September 08, 2020)

**Individual Notifying:** Andrea Miller, Vigilance Manager

**Brainlab Identifier:** CAPA-20200907-002369

**Type of action:** Advice regarding use of device; Device modification

We are writing to advise you of a safety issue with the Brainlab ExacTrac Dynamic software, which may influence the detection of potential patient movement if the system's Beam Hold Control functionality is not used.

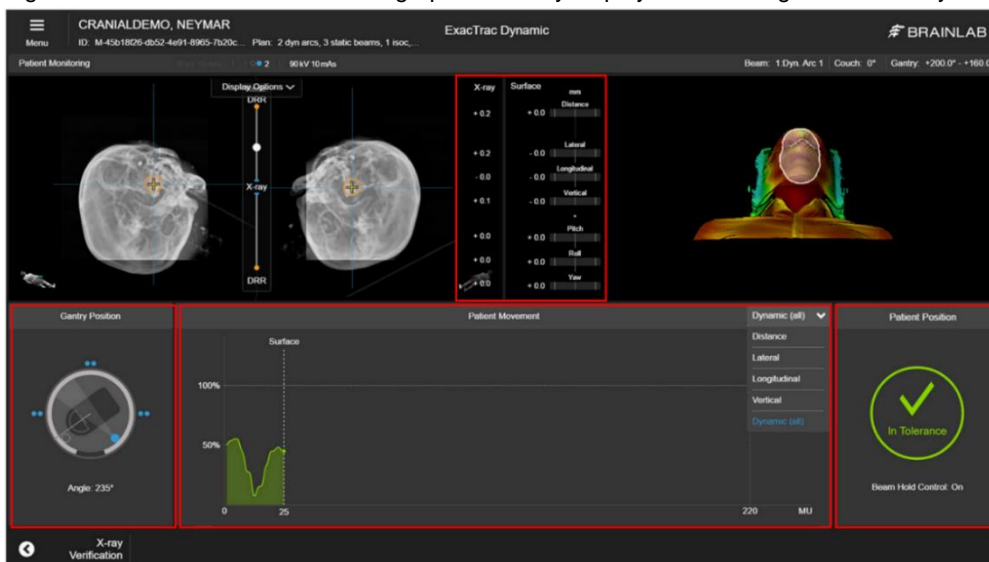
You may have been notified about this issue on Sep 8, 2020 for ExacTrac Dynamic software version 1.0.0 (which is no longer in clinical use). It meanwhile was determined that an additional anomaly contributes to this effect, which is still contained in the versions 1.0.1/1.0.2.

There has been no reported negative impact on patient treatment by any user site due to this issue. The purpose of this Product Notification letter is to provide you with the relevant user information on how this issue occurs and to inform you of the corrective actions Brainlab is taking to address this.

### Effect:

ExacTrac Dynamic monitors patient movement (based on surface/thermal imaging and X-rays) while the Linear Accelerator delivers radiation dose to the patient. The monitoring status is displayed by the software in the form of graphical and numerical indicators, which are constantly updated in real time as the treatment evolves.

Brainlab determined that for high dose treatments, the update of the displayed information in several graphs may be delayed. However, the information itself is correct. Please refer to Figure 1: The red boxes indicate the graphs that may display status changes with a delay.



**Figure 1: Patient Monitoring page: Red boxes indicate graphs that are potentially updated with delay. The displayed status may not correspond to the actual situation.**

To clarify, if the patient movement is outside the defined tolerances, the Beam Hold Control functionality works as intended, if enabled as recommended.

In the rare scenario in which a user relies solely on the information displayed by the Patient Monitoring page, the delayed update of information may lead to a delay in the user detecting the patient movement.

**If a deviation from the patient target position goes undetected or the user detects it with delay and the deviation exceeds clinically acceptable tolerances for the indication being treated, underdosage of the planned target volume and/or an overdosage of healthy tissue could occur.**

The following page details the specific conditions required for this error to occur, along with the affected workflows.

**Details:**

One anomaly contained in ExacTrac Dynamic software version 1.0.0 (as communicated on Sep 8, 2020) had been solved by improving the plotting routine of the Patient Movement graph. Only later an additional anomaly was identified that also contributes to the effect described: Due to an issue with the memory management of ExacTrac Dynamic, an undesired accumulation of memory (memory leak) may occur when plotting Patient Movement graphs containing many data points. The increasing memory consumption may accumulate across beams and even across patient treatments. The memory leak decreases performance of ExacTrac Dynamic and therefore compromises the software's ability to plot the Patient Movement graph in real time. As a result, the graph shows the patient position with an increasing delay that may reach several minutes. This further leads to other elements of the user interface being updated with that same delay (see Figure 1 for affected elements) and delayed button response to user interactions. In extreme cases, it may even lead to unresponsiveness of the ExacTrac Dynamic software.

Whether the issue occurs and to which extent depends on the total amount of delivered Monitor Units (MUs) exceeding a critical threshold of 2500 MU per beam/arc that have accumulated since the ExacTrac Dynamic software was last started.

Since application memory consumption is subject to fluctuations, this threshold represents only the lowest dose limit (based on conservative calculations). In many clinical cases the issue will occur only for significantly higher dose values (esp. if only one beam/arc exceeds the threshold).

The issue could only lead to a potential negative effect for the patient if ALL of the following conditions are fulfilled:

- The critical threshold of 2500 MU per beam/arc was exceeded one or several times since the last start of the ExacTrac Dynamic software
- The patient has moved outside the defined tolerances
- The Beam Hold Control functionality is disabled, or the Beam Hold Control functionality is enabled and the user actively selects to ignore the beam hold

To clarify, the issue does not occur or, if already occurred, the effect does not worsen, for treatments with a delivered dose per beam/arc below the above-mentioned critical threshold.

**Retrospective review:**

For treatments that have already been performed and fulfill the above-mentioned conditions, the patient movement recorded during the treatment can be reviewed in the ExacTrac Dynamic treatment report. The data recorded in the treatment report is correct and not affected by the anomalies.

**User Corrective Action:**

- 1) During treatment planning, ensure that the planned dose per beam/arc is **always below 2500 MU** when using ExacTrac Dynamic versions 1.0.1/1.0.2. You can do so by splitting beams/arcs, if required.  
(Please note that in the Notification of Sep 8, 2020, the values given when using Elekta Linear Accelerators were set too high at 3650 MU.)
- 2) Always keep the Beam Hold Control functionality enabled. If the system holds the beam, do not select "Ignore", but verify the patient position.
- 3) Restart the ExacTrac Dynamic software at least once a day, e.g., at the end of the treatment day, to clear potentially accumulated memory.

Please continue to follow the instructions and warnings as described in the user guide. The following warning in the Clinical User Guide ExacTrac Dynamic is especially relevant:

Beam Hold Control is selected by default for every master template provided by Brainlab. It is recommended to keep this feature selected when designing templates, as well as for plan preparation.

**Brainlab Corrective Action:**

1. Existing customers that are potentially affected receive this product notification information.
2. Brainlab will provide a software revision of ExacTrac Dynamic with the described issue corrected to all affected customers. Brainlab will actively contact you to schedule the update, starting June 2021.

**Please advise the appropriate personnel working in your department of the content of this letter.**

We sincerely apologize for any inconvenience and thank you in advance for your cooperation. If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

**Customer Hotline:**

+49 89 99 15 68 1044 or +1 800 597 5911 (for US customers)

**E-mail:** [support@brainlab.com](mailto:support@brainlab.com) (for US customers: [us.support@brainlab.com](mailto:us.support@brainlab.com))

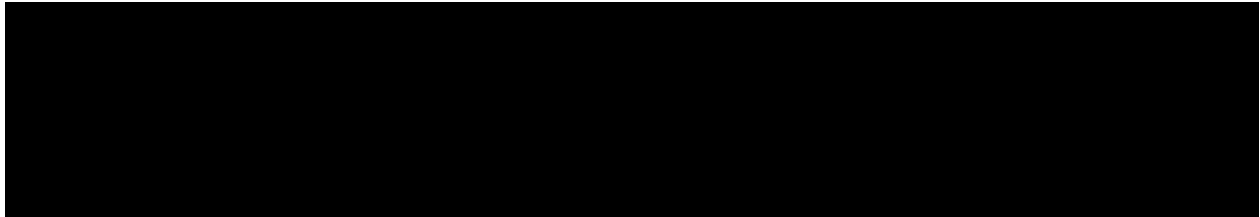
**Fax:** Brainlab AG: + 49 89 99 15 68 5033

**Address:** Brainlab AG (headquarters):

Olof-Palme-Strasse 9, 81829 München, Germany

April 29, 2021

Kind Regards,



## URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

**Subject:** ExacTrac Dynamic Radiation Therapy Patient Positioning System:  
 For high dose treatments, potential patient movement might be displayed to the user with a delay

**Product Reference:** ExacTrac Dynamic 1.0.0

**Date of Notification:** September 08, 2020

**Individual Notifying:** Andrea Miller, Vigilance Manager

**Brainlab Identifier:** CAPA-20200907-002369

**Type of action:** Advice regarding use of device; Device modification

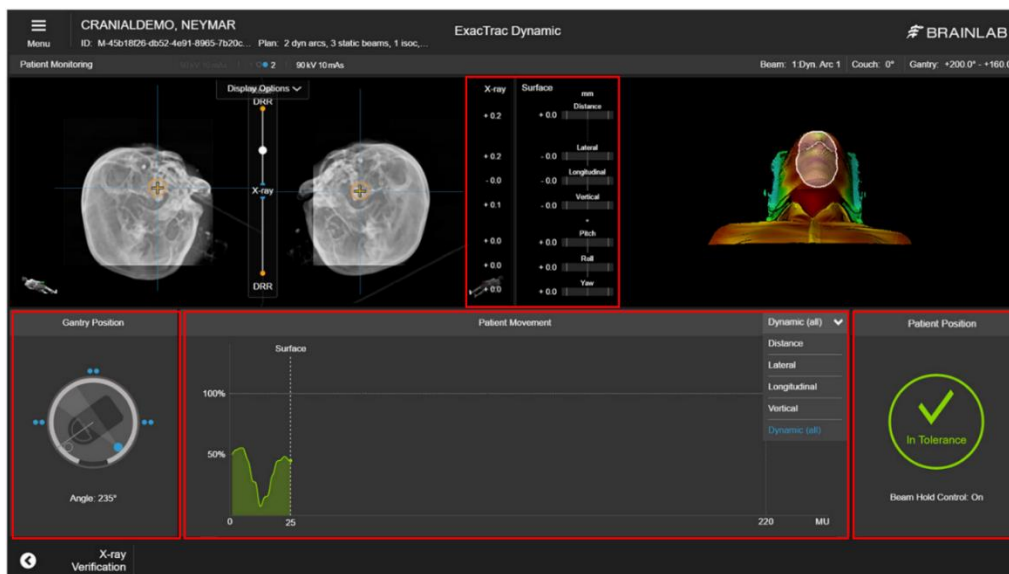
We are writing to advise you of a safety issue with the Brainlab ExacTrac Dynamic software 1.0.0, which may influence the detection of potential patient movement if the system's Automatic Beam Hold functionality is not used.

There has been no reported negative impact on patient treatment by any user site due to this issue. The purpose of this Product Notification letter is to provide you with the relevant user information on how this issue occurs and to inform you of the corrective actions Brainlab is taking to address this.

### Effect:

ExacTrac Dynamic monitors patient movement (based on surface/thermal imaging and X-rays) while the Linear Accelerator delivers radiation dose to the patient. The monitoring status is displayed by the software in the form of graphical and numerical indicators, which are constantly updated in real time as the treatment evolves.

Brainlab determined that for high dose treatments, the update of the displayed information in several graphs may be delayed. However, the information itself is correct. Please refer to Figure 1: The red boxes indicate the graphs that may display status changes with a delay.



**Figure 1: Patient Monitoring page: Red boxes indicate graphs that are potentially updated with delay. The displayed status may not correspond to the actual situation.**

To clarify, if the patient movement is outside the defined tolerances, the Automatic Beam Hold functionality will hold the beam. This functionality is enabled by default in the patient settings and works as intended.

In the rare scenario in which a user relies solely on the information displayed by the Patient Monitoring page, the delayed update of information may lead to a delay in the user detecting the patient movement.

**If a deviation of the patient target position goes undetected or the user detects it with delay and the deviation exceeds clinically acceptable tolerances for the indication being treated, underdosage of the planned target volume and/or an overdosage of healthy tissue could occur.**

The following pages detail the specific conditions required for this error to occur, along with the affected workflows.

**Details:**

The delayed update of displayed information on the Patient Monitoring page is caused by a delayed update of the Patient Movement graph (see Figure 1, in the bottom middle), which plots the patient position deviation versus the delivered dose. This graph is redrawn entirely for each update of the plot. Hence, the time for drawing increases with the number of points in the graph. Since the delivered dose is transmitted from the Linear Accelerator to the ExacTrac system with a high update rate, it may happen that the plotting of the graph is still ongoing when the next update of delivered dose count is received from the Linear Accelerator. As a result, the graph no longer shows the patient position in real time, but rather with an increasing delay that may reach several minutes for high dose treatments. This further leads to other graphs being updated with that same delay (see Figure 1 for affected graphs) and delayed button reactions to user interactions.

Whether the issue occurs and to which extent depends on:

- The planned dose per beam/arc
- The Linear Accelerator dose rate
- The update rate at which the Linear Accelerator communicates the delivered dose to ExacTrac Dynamic

Since these parameters are related in a complex, non-linear way, only the lowest dose limits (based on conservative calculations) are mentioned in the following paragraph; The issue might occur for these dose values or higher values, but in many clinical cases the issue will occur only for significantly higher dose values.

The issue could lead to a potential negative effect for the patient only if ALL of the following conditions are fulfilled:

- The planned dose per beam/arc is:
  - o larger than 1750 MU when using Varian Linear Accelerators
  - o larger than 3650 MU when using Elekta Linear Accelerators
- The patient has moved outside the defined tolerances
- The Automatic Beam Hold functionality is disabled, or the Automatic Beam Hold functionality is enabled and the user actively selects to ignore the beam hold.

To clarify, the issue does not occur for treatments with a planned dose per beam/arc below the above-mentioned dose limits.

**Retrospective review:**

For treatments that have already been performed and fulfill the above-mentioned conditions, the patient movement recorded during the treatment can be reviewed in the ExacTrac Dynamic treatment report. The data recorded in the treatment report is correct.

**User Corrective Action:**

- 1) During treatment planning, ensure that the planned dose per beam/arc is:
  - below 1750 MU when using Varian Linear Accelerators
  - below 3650 MU when using Elekta Linear AcceleratorsYou can do so by splitting beams/arcs, if required.
- 2) Always keep the Automatic Beam Hold functionality enabled, as is the default setting. If the system holds the beam, do not select "Ignore", but verify the patient position.

Please continue to follow the instructions and warnings as described in the user guide. The following warning in the Clinical User Guide ExacTrac Dynamic is especially relevant:

Beam Hold Control is selected by default for every master template provided by Brainlab. It is recommended to keep this feature selected when designing templates, as well as for plan preparation.

**Brainlab Corrective Action:**

1. Existing customers that are potentially affected receive this product notification information.
2. Brainlab will provide a software revision of ExacTrac Dynamic with the described issue corrected to all affected customers. Brainlab will actively contact you to schedule the update, starting October 2020.

**Please advise the appropriate personnel working in your department of the content of this letter.**

We sincerely apologize for any inconvenience and thank you in advance for your cooperation. If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

**Customer Hotline:**

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**E-mail:** [support@brainlab.com](mailto:support@brainlab.com) (for US customers: [us.support@brainlab.com](mailto:us.support@brainlab.com))

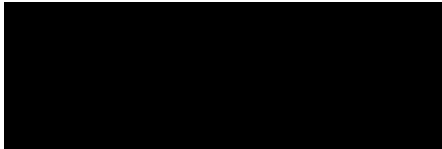
**Fax:** Brainlab AG: + 49 89 99 15 68 5033

**Address:** Brainlab AG (headquarters):

Olof-Palme-Strasse 9, 81829 München, Germany

September 08, 2020

Kind Regards,



Europe: The undersign confirms that the appropriate Regulatory Agency in Europe has been notified of this notice.